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TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
15888 (PC11885A)

In Re Application Of: **Roger C. Adami, et al.**

| Application No. | Filing Date | Examiner | Customer No. | Group Art Unit | Confirmation No. |
|-----------------|--------------------|------------|--------------|----------------|------------------|
| 10/675,130 | September 30, 2003 | Unassigned | 23389 | 1645 | 5705 |

Title: **STABILIZED NAKED DNA COMPOSITIONS**



Address to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

37 CFR 1.97(b)

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

37 CFR 1.97(c)

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

☐ the statement specified in 37 CFR 1.97(e);

OR

☐ the fee set forth in 37 CFR 1.17(p).

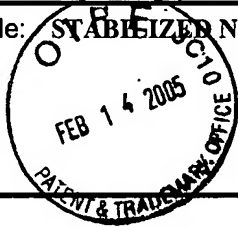
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Payment of Fee

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of _____ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **19-1013/SSMP** as described below.
- ☐ Charge the amount of _____
- ☐ Credit any overpayment.
- ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

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Certificate of Transmission by Facsimile*

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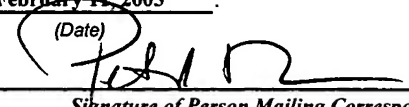
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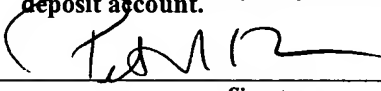
February 11, 2005
(Date)


Signature of Person Mailing Correspondence

Peter I. Bernstein

Typed or Printed Name of Person Mailing Certificate

***This certificate may only be used if paying by deposit account.**



Signature

Dated: **February 11, 2005**

Peter I. Bernstein
Registration No. 43,497
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Garden City, New York 11530
(516) 742-4343

cc: **PIB/ZY:ab**



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Roger C. Adami, et al.

Examiner: Unassigned

Serial No.: 10/675,130

Art Unit: 1645

Filed: September 30, 2003

Docket: 15888 (PC11885A)

For: STABILIZED NAKED
DNA COMPOSITIONS

Dated: February 11, 2005

Confirmation No.: 5705

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

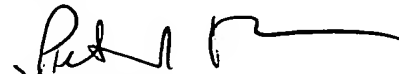
In accordance with 37 C.F.R. §§1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. Wolfert M.A. et al., "Characterization of Vectors for Gene Therapy Formed by Self-Assembly of DNA with Synthetic Block Co-Polymers", *Human Gene Therapy* 7:2123-2133 (1996);
2. Wyman T.B. et al., "Design, Synthesis, and Characterization of a Cationic Peptide that Binds to Nucleic Acids and Permeabilizes Bilayers", *Biochemistry* 36:3008-3017 (1997);

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: February 11, 2005


Peter I. Bernstein

3. Zhang G. et al., "A Cationic Lipid for Rapid and Efficient Delivery of Plasmid DNA into Mammalian Cells", *Biochemical and Biophysical Research Communications* 236:126-129 (1997);
4. Ogris M. et al., "The Size of DNA/Transferrin-PEI Complexes is an Important Factor for Gene Expression in Cultured Cells", *Gene Therapy* 5:1425-1433 (1998);
5. Adami R.C. et al., "Metabolic Stability of Glutaraldehyde Cross-Linked Peptide DNA Condensates", *Journal of Pharmaceutical Sciences* 88(8):739-746 (1999); and
6. Plank C. et al., "Activation of the Complement System by Synthetic DNA Complexes: A Potential Barrier for Intravenous Gene Delivery", *Human Gene Therapy* 7: 1437-1446 (1996).

Applicants are submitting copies of the above-cited references.

Consideration of this Information Disclosure Statement is respectfully requested, since the art provided may be material to the examination of the present application as defined under 37 C.F.R. §1.56.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. § 1.97(b), no statement or fee is required.

Respectfully submitted,




Peter I. Bernstein

Registration No. 43,497

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(516) 742-4343

PIB/ZY:dg/ab

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| Form PTO-1449 U.S. DEPARTMENT OF COMMERCE (REV. 7-80) PATENT AND TRADEMARK OFFICE <div style="text-align: center;"> LIST OF PRIOR ART CITED BY APPLICANT </div> <div style="text-align: center;">  </div> <div style="text-align: center;"> <i>(Use several sheets if necessary)</i> </div> | | Atty. Docket No. (Optional) 15888 (PC11885A) | | Application Number 10/675,130 | | | | | | | |
| | | Applicant(s) Roger C. Adami, et al. | | | | | | | | | |
| | | Filing Date September 30, 2003 | | Group Art Unit 1645 | | | | | | | |
| U.S. PATENT DOCUMENTS | | | | | | | | | | | |
| EXAMINER INITIAL* | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE (if appropriate) | | | | |
| | AA | | | | | | | | | | |
| | AB | | | | | | | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | | | | | | |
| | REF | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | | | | |
| | | | | | | | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">YES</td> <td style="width: 50%;">NO</td> </tr> <tr> <td style="height: 20px;"></td> <td style="height: 20px;"></td> </tr> </table> | YES | NO | | |
| YES | NO | | | | | | | | | | |
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| OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i> | | | | | | | | | | | |
| | | Wolfert M.A. et al., "Characterization of Vectors for Gene Therapy Formed by Self-Assembly of DNA with Synthetic Block Co-Polymers", <i>Human Gene Therapy</i> 7:2123-2133 (1996) | | | | | | | | | |
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| | | Zhang G. et al., "A Cationic Lipid for Rapid and Efficient Delivery of Plasmid DNA into Mammalian Cells", <i>Biochemical and Biophysical Research Communications</i> 236:126-129 (1997) | | | | | | | | | |
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| | | Plank C. et al., "Activation of the Complement System by Synthetic DNA Complexes: A potential Barrier for Intravenous Gene Delivery", <i>Human Gene Therapy</i> 7:1437-1446 (1996) | | | | | | | | | |
| EXAMINER | | | DATE CONSIDERED | | | | | | | | |
| * EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | | | | | | | | |